FIBROMYALGIA TENS IN PHYSICAL THERAPY STUDY (FM TIPS)

SC MEETING – MAY 16-17, 2023
Randomize by PT clinic site – TENS vs. no-TENS

TENS applied during activity – in clinic and at home

Data collected at PT clinic visits electronically and over phone
**CURRENT STATUS**

<table>
<thead>
<tr>
<th>Count</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>PT Clinics selected (6 Healthcare Systems)</td>
</tr>
<tr>
<td>153</td>
<td>Physical Therapists Trained</td>
</tr>
<tr>
<td>27</td>
<td>Clinics Active</td>
</tr>
<tr>
<td>561</td>
<td>Subjects Screened</td>
</tr>
<tr>
<td>247</td>
<td>Subjects Enrolled (55%)</td>
</tr>
<tr>
<td>193</td>
<td>mITT</td>
</tr>
</tbody>
</table>
Figure 1: FM-TIPS Expected and Actual Enrollments

- Projected Enrollment (N=450)
- Actual Enrollment (N=247)
- End of Enrollment with Current Funding
- Expected Completion of Enrollment

A sample size reduction from 600 to 450 was implemented starting in April 2023.

Visit Completion Rate Over Time

Expected numbers for the completion rates are calculated based on the number of active participants exceeding the visit window. Completion rates are pulled from Table 7 of the last weekly report for the month.
## Barriers Scorecard

<table>
<thead>
<tr>
<th>Barriers</th>
<th>Level of Difficulty*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td></td>
</tr>
<tr>
<td>Engagement of clinicians and health systems</td>
<td></td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td></td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td></td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td></td>
</tr>
<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
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</tr>
</tbody>
</table>

*Your best guess! 1 = little difficulty 5 = extreme difficulty*
TOP CHALLENGES

▪ Recruitment
  ▪ Limited care access for patients in rural areas
  ▪ Keeping clinicians engaged for screening
  ▪ Variability in screening and enrollment

▪ Retention
  ▪ Participant changes e-mail or phone
  ▪ Technology
    ▪ internet access/smart phone
    ▪ TENS application

▪ PT Outpatient Practice Staffing
  ▪ Limited time available for study engagement
  ▪ Concerns about lost reimbursement (although paying for this)
  ▪ Reduced staffing
    ▪ 17% vacancy rate for PT
    ▪ office/front desk staff difficult to maintain

▪ Electronic Health Record Extraction
RECENT GENERALIZABLE LESSON LEARNED

- Study team contact with clinicians is critical for recruitment
- Clinicians welcome community engagement with referring providers and community partners
- Need to be creative with strategies to enhance clinician engagement, recruitment and retention of participants
- Not all strategies work for all clinics-each has an independent clinic culture which required individualized approach
DATA SHARING

▪ What is your current data sharing plan and do you foresee any obstacles?
  ▪ Publish data in peer-reviewed journal
  ▪ We have registered our study on ClinicalTrials.gov and on NIH HEAL Initiative, HEAL Data Platform.
  ▪ We will share final data set to Inter-University Consortium for Political and Social Research (ICPSR) repository.
  ▪ We have entered study level information on the CEDAR MetaData Center.

▪ What information did the IRB require about how the data would be shared beyond the study in order to waive informed consent, if applicable?
  ▪ We are not waiving informed consent

▪ What data you are planning to share from your project (individual-level data, group-level data, specific variables/outcomes, etc.)?
  ▪ Individual Level Data, Group level data
DATA SHARING OBSTACLES

- No obstacles yet
- Working with the HEAL Data Platform
Thank you